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08/113,561 08/25/93 ADAMS

T PEKA055  
EXAMINER

18M2/0417

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ART UNIT

PAPER NUMBER

20

1803  
DATE MAILED:

04/17/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined  Responsive to communication filed on 4/3/95  This action is made final.

A shortened statutory period for response to this action is set to expire Three (3) month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1.  Notice of References Cited by Examiner, PTO-892.
2.  Notice of Draftsman's Patent Drawing Review, PTO-948.
3.  Notice of Art Cited by Applicant, PTO-1449. (1)
4.  Notice of Informal Patent Application, PTO-152.
5.  Information on How to Effect Drawing Changes, PTO-1474.
6.

Part II SUMMARY OF ACTION

1.  Claims 2-4, 47 + 50-67 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2.  Claims 1, 5-46 448-49 have been cancelled.

3.  Claims \_\_\_\_\_ are allowed.

4.  Claims 2-4, 47 + 50-67 are rejected.

5.  Claims \_\_\_\_\_ are objected to.

6.  Claims \_\_\_\_\_ are subject to restriction or election requirement.

7.  This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8.  Formal drawings are required in response to this Office action.

9.  The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are  acceptable;  not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10.  The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been  approved by the examiner;  disapproved by the examiner (see explanation).

11.  The proposed drawing correction, filed \_\_\_\_\_, has been  approved;  disapproved (see explanation).

12.  Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has  been received  not been received  been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14.  Other

EXAMINER'S ACTION

5           **Status of the Application.**

The Art Unit location of your application in the PTO has changed. To aid in correlation of any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1803.

10          Claims 1, 5-46 and 48-49 have been canceled. Claims 2-4, 47, 56-57 and 61 have been amended. Claims 2-4, 47 and 50-67 are the only claims currently pending contrary to Applicants statement at page 6 of the **Remarks**.

The information disclosure statement (IDS) filed 10/14/94 along with a check for \$210 is noted. The citations therein have been considered.

15          The IDS filed in this application on January 3, 1995 was filed after the first action and more than three months after filing the application. Although it is Applicants belief that such information was placed before the examiner in the parent of this CIP 37 CFR 1.97 has no provision to exclude either certification or payment of a fee for IDS consideration. Consequently a fee of \$210 has been charged to Applicants deposit account number.

20          In view of the papers filed January 3, 1995, it has been found that this application, as filed, through error and without any deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48. The inventorship of this application has been changed by deleting as inventors: Adams, Chambers, Chomet, Daines, 25 Glassman, Laccett., Lemaux, Mangano, Mann, O'Brien, Rice, Spencer, Start, Vetsch, Willetts, and Zachwieja.

30          The amendment filed January 3, 1995 is objected to under 35 U.S.C. § 132 because it introduced new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The text newly presented at page 150 under heading **G**.

5           Applicant is required to cancel the new matter in response to this Office Action. Note that Applicants previous amendment to cancel the phrase "Two samples were". leaves the solitary word "agent." in its place. It is suggested that the word agent be deleted.

**Issues under 35 U.S.C. § 101.**

10          The rejection of claims 2-4 are rejected under 35 U.S.C. § 101 as set forth at page 3 of the previous Office Action is withdrawn in view of amendment.

15          The provisionally rejection of claims 44-46 under 35 U.S.C. § 101 as claiming the same invention as that of claim 33-35 of copending application Serial No. 07/636089 as set forth at pages 3-4 of the previous Office Action is withdrawn in view of Applicants cancellation of claims 44-46.

20          Claims 2-4, 47, 56-57 and 61, newly amended, are provisionally rejected and claims 50-55, 58-60 and 62-67 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-68 of copending application serial no. 07/508045 for the reasons of record as set forth at pages 3-4 of the previous Office Action.

25          Applicants urge that the subject matter of the '045 case is distinct form that of claims 47-67 of the instant application. Applicants arguments are considered as if they apply to claims 2-4 and 47-67 as these claims are currently pending and have been or remain rejected. It is Applicants position that the specification '045 in no way provides a teaching, suggestion or motivation for the person having ordinary skill in the art to make the invention employing the specific DNA of claim 47-67. The examiner notes that all the claimed DNA, genes, and the like, were previously known in the art and their insertion into a maize plant is made obvious by '045 unless the DNA of interest is demonstrated to function in a way not commensurate with its known and expected function. For example, if a *Bt* gene placed in maize would function to increase sugar content this would be both an unexpected and novel outcome of the invention. The rejection is maintained.

5 **Issues under 35 U.S.C. § 112.**

Claim 47, newly amended, is rejected under 35 U.S.C. § 112, second paragraph, and claims 60 and 63-67 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the 10 reasons of record as set forth at page 4 of the previous Office Action.

Applicants urge that the format used is specifically noted in MPEP 706.06(y). Note that this section of the MPEP specifically uses the term "consisting of" and not the "comprising" language of the instant claim. The rejection is maintained.

15 The rejection of claim 43 under 35 U.S.C. § 112, second paragraph, as set forth at page 4 of the previous Office Action is withdrawn in view of Applicants' cancellation of claim 43.

20 The rejection of claims 47 and 57 under 35 U.S.C. § 112, second paragraph, as set forth at pages 4/5 of the previous Office Action is withdrawn in view of Applicants' amendment.

The rejection of claims 1-15, 19-21, 24-29, 32-58 & 60-67 under 35 U.S.C. § 112, first paragraph as set forth at page 5 of the previous Office Action is withdrawn upon further consideration.

25 Attention is directed to Applicants' copy of the interview summary form of July 7, 1994 regarding the rejection and not merely the objection to the claims noted above.

**Issues of Prior Art.**

In the interest of clarity the following rejection is repeated in its complete and intended form. The examiner notes Applicants' confusion as to the basis of 30 the rejection in that the rejection under 35 U.S.C. § 103 was inadvertently inserted

5 within the body of the prior rejection under 35 U.S.C. § 112, first paragraph. However, as Applicant proceeded correctly based on his assumption as to the actual basis of the rejection the examiner views that neither harm nor delay was incurred. Still a further substantive response will be considered fully if Applicants decide to continue prosecution of the instant application.

10 Claims 2-4 and 47-67 are provisionally rejected under 35 U.S.C. § 103 as being obvious over copending application serial number 07/508,045.

Application 07/508,045 discloses the fertile transgenic maize in which the genome is augmented by the addition of non-native DNA. The instant application and '045 differ in the precise recitation of the DNA of interest. The instant specification acknowledges that all species of DNA employed herein were well known in the art. The person having ordinary skill in the art would view the choice of DNA that was previously well known in the art as mere experimenter preference in the absence of evidence the same functioned in a means not previously known. Accordingly the person having ordinary skill in the art would view the instant invention as clearly *prima facie* obvious in the absence of sufficient, clear, and convincing evidence to the contrary.

Copending serial number 07/508.045 has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. § 102(e) if patented. This provisional rejection under 35 U.S.C. § 102(e) is based upon a presumption of future patenting of the conflicting copending application.

This provisional rejection under section 102(e) might be overcome either by a showing under 37 CFR 1.132 that any unclaimed invention disclosed in the copending application was derived from the inventor of this application and is thus not the invention "by another", or by a showing of a date of invention of any unclaimed subject matter prior to the effective U.S. filing date of the copending application.

5         Applicants' arguments have been carefully considered and are not deemed  
persuasive. Applicants position appears to be that the mere cloning of genes  
would not make every gene obvious. The examiner would of course agree,  
however, in the instant case each DNA species was previously isolated, cloned  
and its function known -- that is there is nothing novel about the specific DNA. As  
10       the inventive aspect of both '045 and '561 resides in the making of transgenic  
plants the earlier filed application clearly makes the latter obvious. In terms of the  
difference between enablement and obviousness the existence of two different  
standards occur because they have a different statutory basis and this alone  
does not on its face make holding both enablement and obviousness  
15       inconsistent. Enablement carries with its the dual aspect of defining of the  
invention that Applicant intents to enable, that is Applicant must enable an  
invention circumscribed by the claims, i.e., a specific invention. Merely reciting  
that DNA is not normally found in maize or non-native to maize does not describe  
or enable the invention. It remains obvious that a person having ordinary skill in  
20       the art inserting a *Bt* gene into the maize genome in which it is expressed at  
biologically effective levels would expect it to function as *Bt* was known to  
function transgenomically in other species. That would be clearly *prima facie*  
obvious.

25       The rejection of claims 1, 2, 5, 9-16, 43-46 and 61 under 35 U.S.C. § 103  
as set forth at page 7 of the previous Office Action is withdrawn in view of  
Applicants' cancellation of claims 1, 2, 5, 9-16, 43-46 and amendment to claim  
61.

30       Claims 2-4, 47, 56-57 and 61, newly amended, are rejected and claims .  
Claims 50-55, 57-60 and 62-67 remain rejected under 35 U.S.C. § 103 as obvious  
over Goldman et al. in view of Applicants acknowledged state of the prior art as  
set forth at pages 7-8 of the previous Office Action.

Applicants' arguments have been carefully considered and are not deemed  
persuasive. Goldman et al. contrary to assertions used appropriate tests to  
establish transformation. Note use of hygromycin resistance other than

5 kanamycin resistance. Note also that the assay employed specifically avoided the problem of Christou et al. Regarding the allegations as to the enablement of the specification of Goldman et al. which was examined based on the level of skill and knowledge available to the examiner at the time, each application is examined on its own merits. Goldman et al. is considered enabled for the  
10 production of transgenic maize plant via *Agrobacterium tumefaciens* mediated transformation. Concerning Applicants' citation of Bolton et al. and Shun et al. the method employed therein using agroinfection clearly demonstrates that *Agrobacterium* can infect maize and introduce the Ti plasmid into the plant which further evidences that *Agrobacterium tumefaciens* can in fact transform maize as  
15 was taught by Goldman et al. The fact than the viral DNA acted like viral DNA and not Ti DNA would have been expected in the art. Applicants have asked for additional data from Goldman et al. to establish that their method works. If Applicants are requesting that the Office reexamine Goldman et al. the examiner suggests that a formal request for reexamination be made as all US patents are  
20 considered valid. If Applicants are suggesting that the examiner query the inventors of Goldman et al. the examiner has neither the statutory authority nor means to request declaratory evidence from an inventor of an **issued** US patent. This is Applicants burden.

The rejection of claim 7 under 35 U.S.C. § 103 as set forth at page 8 of the  
25 previous Office Action is withdrawn in view of Applicants cancellation of claim 8.

The rejection of claim 20 under 35 U.S.C. § 103 as set forth at pages 8/9 of the previous Office Action is withdrawn in view of Applicants cancellation of claim 20.

The rejection of claim 25 under 35 U.S.C. § 103 as set forth at page 9 of the previous Office Action is withdrawn in view of Applicants cancellation of claim 25.

Please note the interview summary form of 7/7/94.

5 The rejection of claims 1-4 and 9 under 35 U.S.C. § 103 as set forth at pages 9/10 of the previous Office Action is withdrawn in view of Applicants cancellation of claim 1 and 9 and amendment to claims 2-4.

No claim is allowed.

10 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15 **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.**

20 Any inquiry concerning this or earlier communication from the examiner should be directed to Gary Benzion, Ph.D whose telephone number is (703) 308-1119. The examiner can normally be reached on Monday-Friday from 8 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas W. Robinson can be reached on (703)-308-2897.

30 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

35 Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with

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- 5 the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).  
The CM1 Fax Center number is (703)-305-3014. Informal communication may be sent via facsimile at 703-308-7362. The examiner should be notified at extension X-1119 of any informal communication prior to its transmittal.

Benzion  
10 04/14/95



GARY BENZION  
PRIMARY EXAMINER  
GROUP 1800